Subject Name: _____Last 4 SSN:_____ Date: _____

Title of Study: Implementation of Brief Insomnia Treatments – Clinical Trial

Principal Investigator: Adam Bramoweth, PhD VAMC: Pittsburgh (646)

LAY TITLE: Insomnia Study

STUDY CONTACT INFORMATION:
If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call Dr. Adam Bramoweth at (412) 360-2806, or any of the investigators listed below.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call Dr. Adam Bramoweth at (412) 360-2806, at any time of the day. In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call Dr. Adam Bramoweth at (412) 360-2806, and after-hours or on weekends call 1-866-785-9015 and tell the operator that you are a research subject from the Pittsburgh VA in the study, "Implementation of Brief Insomnia Treatments – Clinical Trial" and need to speak with Dr. Adam Bramoweth. Then give the operator a phone number where you can be reached. The operator will get in touch with Dr. Bramoweth or another person listed below who will call you back."

PRINCIPAL INVESTIGATOR:
Adam Bramoweth, PhD
VA Pittsburgh Healthcare System
Research Office Building, 151R
University Drive C
Pittsburgh, PA 15240
(412) 360- 2806

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CO-INVESTIGATORS:
Matthew Chinman, PhD
VA Pittsburgh Healthcare System
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(412) 360 – 2438

Charles Atwood, MD
VA Pittsburgh Healthcare System
University Drive C
Pittsburgh, PA 15240
(412) 360 – 6823

Ada Youk, PhD
VA Pittsburgh Healthcare System
Research Office Building, 151R
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Pittsburgh, PA 15240
(412) 360 – 2124

STUDY SPONSOR:
VA Health Services Research & Development
Additional information regarding the study sponsor can be provided upon request.

PURPOSE OF THE RESEARCH STUDY: The purpose of this research study is to compare the effectiveness of two non-medication treatments for insomnia. Cognitive Behavioral Therapy for Insomnia (CBTI) is widely used throughout the Veterans Health Administration (VHA) and at VA Pittsburgh Healthcare System (VAPHS). Brief Behavioral Treatment of Insomnia (BBTI) is briefer than CBTI but is not as commonly used in the VHA or at VAPHS. This study will compare the two interventions.

You are being asked to participate in this research study because you are a Veteran with insomnia symptoms.

This study will enroll up to 300 Veterans at VAPHS.

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A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

To help you better understand the study, the next section describes the study. Please feel free to ask any questions you want. We want you to understand as much as possible about what is involved in the study before you decide whether or not to participate.

DESCRIPTION OF THE RESEARCH STUDY:

1. **Location:** This study will take place at VAPHS (University Drive Campus, H.J. Heinz Campus, and the Research Office Building).

2. **Study Procedures:**
   a. *Diagnostic Interview and Baseline Assessment*: You will be asked to answer questions regarding symptoms of sleep disorders and psychiatric disorders, such as depression, anxiety, and posttraumatic stress. You will also be asked to complete several brief pen-and-paper self-report questionnaires. This process may take up to 1 to 2 hours. During this process we may identify symptoms or diagnoses that are not in your medical record. If so, with your permission, we will notify your Primary Care Provider and Behavioral Health Provider. Unless the identification of a diagnosis is part of the exclusion criteria (reasons you will not qualify in the study), you will remain enrolled in the study. Please note that while we are looking for symptoms of sleep and psychiatric disorders, this is not the same as regular medical care.

   b. *Randomization to Intervention*: If you are eligible after completing the Diagnostic Interview, then you will be randomized to one of the two intervention groups: Brief Behavioral Treatment of Insomnia (BBTI) or Cognitive Behavioral Therapy for Insomnia (CBTI).

   c. *Intervention*: BBTI and CBTI will be delivered by licensed psychologists at VAPHS. Both interventions are supported by research evidence and are delivered both at VAPHS and in the community. During intervention, you will meet with your assigned clinician approximately once each week (BBTI: 4 sessions within 5 weeks; CBTI: 5 sessions within 8 weeks). The intervention will occur either in-person or by telephone, and each session will last between

approximately 20 minutes to 60 minutes, depending on your assigned group. During the intervention you will also be asked to complete several brief pen-and-paper self-report questionnaires both at home and during sessions.

d. *Session Audio Recordings*. On weeks with face-to-face sessions, the sessions with the study clinician will be audio recorded. This is done to verify that the study clinicians give the same information to all participants.

e. *Follow-Up Assessments*. After the intervention is complete, you will be asked to complete several brief pen-and-paper self-report questionnaires (up to 30 minutes to complete) at three time points: immediate post-intervention, 3-month follow-up, and 12-month follow-up. These measures can be completed during an in-person visit with a member of the research team or can be mailed to you.

f. All study procedures are for research purposes only and do not represent usual care.

3. **Data:** All data collected will only contain a unique study ID number and the date.
   a. Data will be stored in a database located on a secure VA server. No data will be disclosed outside of VA. Any written/hard copy information you give us will be kept in a locked file cabinet at VAPHS Research Office Building. To keep your information confidential, you will be assigned a unique study ID number that will not reveal your identity. The key to the study ID numbers will be kept on file in a secure VA server. Data will be marked using your unique study ID so that you cannot be identified. Study ID numbers are assigned when participants enroll in the study (complete informed consent) and do not reflect any part of your name or other personal information.

   b. To further protect your identity on the audio recordings, the study clinician will be instructed and will instruct you that names are not going to be used during the session. The recorder will be kept in the clinician's office, in locked file cabinets, and once a month, a study staff member will download the recordings to the study's secure database. Recordings will be identified by your unique ID number and session number only. After you complete intervention, the recordings will be available to the study investigators to review.

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c. Only approved research staff for this study will have access to the data.

4. **Participation**: Participation in this study, including the initial interview, intervention, and follow-up may last approximately 12-15 months. Your participation in this study will end upon completion of all study procedures. If you decide to withdraw from the study before the completion of all study procedures, your participation will end immediately upon your withdrawal.

   If you are currently using sleep medications (such as Trazodone, Zolpidem, or Temazepam), to be eligible, we ask that your medication and dosage has not changed in the past month, and will remain unchanged for the duration of the treatment phase of the study (i.e., 4-8 weeks). If you are currently using other psychotropic medications (such as antidepressants or anti-anxiety drugs), to be eligible, we ask that your medication and dosage has not been changed in the past 2 months, and will remain unchanged for the duration of the treatment phase of the study (i.e., 4-8 weeks). Any changes in medication are a decision between you and your prescribing physician.

5. **Additional Studies**: If you are eligible for this study, and enroll and participate in this study, you will be eligible to enroll in a new study: "Implementation of Brief Insomnia Treatments – Qualitative Needs Assessment." This is a separate study that will involve a separate informed consent process; however, you are under no obligation to participate in the new study. This new study involves completing an audio-recorded interview about your thoughts and feelings about treatments of insomnia and how insomnia care is delivered. You will be asked about participating in the new study at a later date and no decision is required at this time.

   Are you willing to be re-contacted about the new study "Implementation of Brief Insomnia Treatments – Qualitative Needs Assessment"? If you agree to be re-contacted, information from the current study may be shared with the new study.

   ○ YES, I agree to be re-contacted ○ NO, I do not agree to be re-contacted.

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RISKS AND BENEFITS:

PARTICIPATING IN RESEARCH MAY INVOLVE UNFORSEEABLE RESULTS

The primary risk involved in participating in this study is that there is potential for symptoms of insomnia to not improve or potentially worsen in either intervention arm, BBTI or CBTI. There is the possibility of a decrease in sleep quantity and/or quality related to intervention. However, these risks are a normal and expected part of participating in behavioral sleep interventions and are similar to the risks involved in participating in the intervention in a clinical setting. By participating in this study, you may also be attending more clinical visits than you would normally, as well as completing self-report questionnaires and measures frequently such as a daily sleep diary, and questionnaires about sleep and mood symptoms on a weekly basis during the intervention. If you are not improving in 4-8 weeks, let your study doctor/provider know, along with your clinical care team, and other treatments/medications may be prescribed to you.

Other potential risks include emotional or psychological discomfort related to answering questions as part of the diagnostic interview and self-report questionnaires. You are encouraged to ask the research staff for a break if you feel yourself becoming distressed. You can also refuse to answer any questions that make you uncomfortable and/or distressed and you can stop the interview/assessment at any time; however, this may result in participation in the study ending. You may also become fatigued from answering the questions during the diagnostic interview and/or on the self-report questionnaires. In the instance that you experience discomfort, you can ask the research staff for a break and you can resume when ready.

Because there may be other risks associated with participating in multiple research studies, you must tell the research staff about any other studies you are currently participating in, both within and outside of the VA.

Confidentiality: Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you. All hard/paper copies of the surveys/questionnaires completed by you will be stored in a secured location at the

VAPHS Research Office Building. Data collected during all phases of the study will be entered into an electronic database that is stored on a secure VA server. Any data collected that contain information that could be used to identify you (such as your name, address, date of birth, etc.) will be stored separately from any information that does not contain identifiers. Only those individuals who are authorized to review your information will have access to it.

In addition, Federal agencies, including but not limited to, the Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), VA's Office of Research Oversight (ORO) and the VA Office of the Inspector General (OIG) may have access to your research records. The Food and Drug Administration (FDA) may also choose to inspect research records, which may include your individual medical records, if this research is FDA-regulated. Research records, just like hospital medical records, may be released or disclosed pursuant to applicable federal and state law as well as to federal and state agencies that are responsible for oversight of medical research. Additionally, any medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under federal laws and regulations. Finally, you consent to the publication of the study results so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed.

You may benefit from participating in this study. Direct benefits may include a reduction of your insomnia symptoms. The knowledge to be gained from this research can potentially improve the way insomnia is treated for Veterans and non-Veterans.

ALTERNATIVES TO PARTICIPATION:
There may be other studies that you qualify for. Talk to your provider about such options.

You may also choose to seek treatment for insomnia, including BBTI and CBTI, without participating in this study. You may also choose to seek pharmacological treatment for insomnia. Talk to your provider about insomnia treatment options. You also have the alternative not to participate in this research study.

NEW FINDINGS:
You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate.

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INVESTIGATOR INITIATED WITHDRAWAL:
The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury. Additionally, the investigator's sponsor or the Institutional Review Board can stop the study anytime if important new findings develop during the study.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW:
Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. You may choose to withdraw from the intervention phase of this study but continue to participate in the post-intervention and follow-up assessments.

Your doctor may also be involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. You are under no obligation to participate in this or any other research study offered by your doctor. Before you agree to participate in this research study, or at any time during your participation in this study, you may discuss your care with another doctor who is not associated with this research study.

MEDICAL TREATMENT:
In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities.

However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION:
If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If

compensation is available the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

COST AND PAYMENTS: You or your insurance will not be charged for any costs related to the research. However if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in federal regulations as a "category 7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study.

You may receive up to $200 to cover your time and effort for completion of all phases of this study. Payments will occur after completion of the following visits:

- Diagnostic interview, $40
- Post-intervention follow-up, $100
- 3-month follow-up, $30
- 12-month follow-up, $30

Except in limited circumstances, payments issued through VA are generated by Electronic Funds Transfer (EFT). Therefore, in order to receive payment associated with your participation in this study, you must be willing to receive EFT and to provide banking information to VA, if that information has not already been provided. In addition, due to limitations in the Financial Management System, payments made to you will generate Internal Revenue Service (IRS) Form 1099 regardless of amount. Payments will be reported to the IRS as income and your social security number will be used for this purpose.

If you are randomized but do not complete treatment, you will be offered $30.00 for filling out follow-up measures at each approximate time point: post-intervention follow-up, 3-month follow-up, and 12-month follow-up.

RECORD RETENTION:
Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule, or longer, if required by other Federal regulations.

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RESEARCH SUBJECTS' RIGHTS:

You have read or have had read to you all of the above. Dr. Adam Bramoweth or his authorized representative has explained the study to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you (or the person representing you) have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You will receive a copy of this signed consent form.

If you have any questions about your rights as a participant in this study, or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at (412) 360-2394.

As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

By signing this form, you agree to participate in this research study.

_____	_____	_____
Subject's Signature	Date	Time
_____	_____	_____
Investigator/Person Obtaining Consent	Researcher (Print)	Date

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